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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

JOIKE, MICHELE K

ART UNIT PAPER NUMBER

1636

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 10/713,113 | Applicant(s) BRENNER ET AL. | |
| | Examiner Michele K. Joike, Ph.D. | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Objections

Claim 2 is objected to because of the following informalities. There is a forward slash between the words "into" and "onto", which should be replaced with an "or". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

In claim 2, in the second step, "some of the sample" is introduced.

However, in claims 3 and 4, "a sample of interest" is introduced. This language renders the claims indefinite as it is unclear what "a sample of interest" entails. It could be read to be a species of "some of the sample", or a different sample.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the

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reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-21, 26-29 and 35-37 of U.S. Patent No. 6,306,621. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46

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USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993), *In re Longi*, 759 F.2d 887, 224 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 5, 6 and 9 are generic to all that is recited in claims 19, 20, 21 and 26 of U.S. Patent No. 6,306,621. That is, claims 19, 20, 21 and 26 of U.S. Patent No. 6,306,621 fall entirely within the scope of claims 1, 5, 6 and 9 or, in other words, claims 1, 5, 6 and 9 are anticipated by claims 19, 20, 21 and 26 of U.S. Patent No. 6,306,621. Specifically, a method of detecting the presence of *E. coli* and/or other coliforms in a sample comprising the steps of: (1) applying a medium containing at least one indicator chosen from galactosides and glucuronides, and an agent used to suppress the growth of non-coliform gram-negative bacteria to a support, (2) applying a portion of said sample to be evaluated for the presence of *E. coli* and/or coliforms on the support prepared in step (1), (3) incubating the product of step (2) for a time sufficient to cause evidence of growth of *E. coli* and other coliforms as represented by color change and/or fluorescence, and (4) observing the medium for color changes and/or fluorescence to detect the presence or absence of *E. coli* and/or other coliforms of claim 1 includes a method of simultaneously detecting the presence of *E. coli* and of other coliforms in a sample comprising the steps of: (1) applying a medium containing a galactoside, a glucuronide, and an agent used to suppress growth of non-coliform gram negative bacteria to a support, wherein said galactoside is a chromogen- or fluorogen-galactoside, and said glucuronide is a chromogen- or fluorogen-glucuronide, (2) applying a portion

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of said sample to be evaluated for presence of *E. coli* and coliforms to the support prepared in step (1), (3) incubating the product of step (2) for a time sufficient to cause evidence of growth of *E. coli* and other coliforms as represented by color change and/or fluorescence, and (4) observing the medium for color changes and/or fluorescence to detect presence or absence of *E. coli* and other coliforms of claim 19 of U.S. Patent No. 6,306,621.

Also, the method of detecting of claim 1 wherein the agent used to suppress the growth of non-coliform gram-negative bacteria is Cefsulodin; wherein the Cefsulodin is present at a concentration of from 1 to 25 mg/L; and, wherein the medium applied to the support contains a solidifying agent as in claims 5, 6 and 9 includes the method of claims 19-21 of U.S. Patent No. 6,306,621 wherein the agent used to suppress growth of non-coliform gram negative bacteria is Cefsulodin; wherein the Cefsulodin is present at a concentration of from 1 to 25 mg/L; and, wherein the medium applied to the support contains a solidifying agent as in claims 20, 21 and 26 of U.S. Patent No. 6,306,621.

Claims 27, 28, 29, 35, 36 and 37 of U.S. Patent No. 6,306,621 fall entirely within the scope of claims 2, 3, 4, 7, 8 and 10 or, in other words, claims 2, 3, 4, 7, 8 and 10 are anticipated by claims 27, 28, 29, 35, 36 and 37 of U.S. Patent No. 6,306,621. Specifically, a method of detecting *E. coli* and/or other coliforms in a sample in which one wishes to determine the presence or absence of *E. coli* and/or other coliforms comprising the steps of: (1) preparing a growth medium containing at least one indicator chosen from galactosides and glucuronides, and

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an agent used to suppress the growth of non-coliform gram negative bacteria, (2) introducing some of the sample which is to be observed to determine the presence or absence of E. coli and/or other coliforms into/onto the preparation of step (1), (3) incubating the product of step (2) for a time sufficient to cause evidence of growth of E. coli and other coliforms as represented by color change and/or fluorescence, and (4) observing the medium for color changes and/or fluorescence to detect the presence of E. coli and other coliforms of claim 2 includes a method of simultaneously detecting E. coli and other coliforms in a sample in which one wishes to determine presence or absence of E. coli and/or other coliforms comprising the steps of: (1) preparing a growth medium containing a galactoside, and a glucuronide, and an agent used to suppress growth of non-coliform gram negative bacteria, wherein said galactoside is a chromogen- or fluorogen-galactoside, and said glucuronide is a chromogen- or fluorogen-glucuronide, (2) introducing some of the sample which is to be observed to determine presence or absence of E. coli and/or other coliforms into/onto the preparation of step (1), (3) incubating the product of step (2) for a time sufficient to cause evidence of growth of E. coli and other coliforms as represented by color change and/or fluorescence, and (4) observing the medium for color changes and/or fluorescence to detect presence of E. coli and other coliforms of claim 27 of U.S. Patent No. 6,306,621.

Also, the method of detecting of claim 3 wherein a sample of interest is introduced by stabbing with a solid object that has been exposed to said sample of interest; wherein a method of claim 4 wherein, in step (2), a sample is

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introduced using a loop; wherein the agent used to suppress the growth of non-coliform gram-negative bacteria is Cefsulodin; wherein the Cefsulodin is present at a concentration of from 1 to 25 mg/L; and, wherein the medium contains, additionally, a solidifying agent as in claims 3, 4, 7, 8, and 10 include the method of detecting of claim 27 of U.S. Patent No. 6,306,621 wherein the agent used to suppress growth of non-coliform gram negative bacteria is Cefsulodin; wherein the Cefsulodin is present at a concentration of from 1 to 25 mg/L; wherein, in step (2), a liquid sample is introduced by stabbing with a solid object that has been exposed to said liquid sample of interest; wherein, in step (2), a liquid sample is introduced using a loop; and, wherein the medium contains, additionally, a solidifying agent.

Allowable Subject Matter

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele K Joike, Ph.D.
Examiner
Art Unit 1636


DAVID GUZO
PRIMARY EXAMINER
